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IS 13366 (1992): Resuscitators intended for use with humans
[CHD 8: Occupational Safety, Health and Chemical Hazards]



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Bhartrhari—Nitiśatakam

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भारतीय मानक

मनुष्यों के लिए पुनर्जीवन यंत्र — विशिष्ट

Indian Standard

RESUSCITATORS INTENDED FOR USE
WITH HUMANS — SPECIFICATION

UDC 614'894

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BUREAU OF INDIAN STANDARDS
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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Industrial Safety Sectional Committee had been approved by the Chemical Division Council.

This standard applies to ventilatory resuscitator, that is, small portable ventilators designed to be used in emergencies both outside and inside hospitals. These devices are intended for use by trained personnel for emergency use.

The effective and safe use of a resuscitator is determined not only by the performance of the resuscitator, but also by the skill of the operator. This standard does not describe the content of the training programmes to develop such skill and does not state who should or should not use a resuscitator. This will be determined by the organizations involved in teaching resuscitation.

Annexure A details test methods and forms an integral part of this standard. Annexure B provides tables of resistances and compliances required to set up the test lung. Annexure C gives a rationale for various clauses in this standard and is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been given. Annexures D and F provide advice concerning materials to be used in resuscitators and face masks.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

RESUSCITATORS INTENDED FOR USE WITH HUMANS — SPECIFICATION

1 SCOPE

This standard specifies minimum performance and safety requirements of ventilatory resuscitators intended for use with industrial workers. It specifies the performance of gas-powered ventilatory resuscitators which are portable and designed for use in emergency situations to provide lung ventilation to individuals whose breathing is inadequate. Resuscitators are designed for adults.

2 REFERENCES

IS 3745 : 1978 'Yoke type valve connections for medical gas cylinders (*first revision*)' is a necessary adjunct to this standard.

3 TERMINOLOGY

3.1 For the purpose of this standard, the following definitions shall apply.

3.1.1 Resuscitator

Portable device used in emergency situations to provide lung ventilation to individuals whose breathing is inadequate.

3.1.2 Static Compliance, C

Volume change of gases in the compartment produced by a unit of pressure change, expressed in litres per kilopascal (l/kPa).

3.1.3 Resistance

Pressure drop per unit of flow at a specified flow, expressed in kilopascals per litre per second (kPa/l/s).

NOTE — According to conventional practice, this has generally been expressed in centimetres of water per litre per second (cm H₂O/s).

3.1.4 Ventilatory Cycle

Cycle comprising the inspiratory phase plus the expiratory phase.

3.1.5 Tidal Volume, V_d

Volume of gas, expressed in millilitres, entering or leaving the patient or the lung model during the inspiratory or expiratory phase time. The physical conditions under which gas volumes are measured should be given.

3.1.6 Minute Volume, V_E^2

Volume of gas expressed in litres per minute, entering or leaving the patient or the lung model. The physical

conditions under which measurement is made should be given.

3.1.7 Stroke Volume

Volume of gas deliverable from the resuscitator to the end of the patient connector during an inspiratory phase of ventilatory cycle.

3.1.8 Airway

Passageway for gas into and out of the lungs.

3.1.9 Demand Valve

Device delivering a flow of gas when actuated by a change in pressure created by the inspiratory efforts of the patient.

3.1.10 Patient Valve

Valve that directs gas into the lungs for the inspiratory phase and into the atmosphere during the expiratory phase.

3.1.11 Patient Connectors

That part of the resuscitation apparatus which connects directly to a face mask or an appropriate mating airway device.

3.1.12 Patient Connection Port

Opening at the patient end of the resuscitator which is connected either to a tracheal tube or a face mask.

3.1.13 Expiratory Port

Opening through which gases and/or vapours pass from the patient during exhalation.

3.1.14 Delivered Oxygen Concentration

Average concentration of oxygen in the gas delivered from the resuscitator.

3.1.15 Apparatus Dead Space, $V_{D, app}$

That volume of previously exhaled gas which is delivered from the resuscitator in the succeeding inspiratory phase.

3.1.16 Gas-powered Resuscitator

Resuscitation device powered by the energy of compressed gas.

3.1.17 Automatic Resuscitator

Apparatus in which the cyclic flow of gas for inflation of the lungs is independent of any inspiratory effort of the patient or repetitive action of the operator.

NOTE — The expiratory phase may also be automatically cycled.

3.1.18 Back Leak

Volume of exhaled gas which does not pass through the expiratory port but returns to the resuscitator.

3.1.19 Forward Leak

Volume of gas produced by the resuscitator during the inspiratory phase which does not pass through the patient port to the patient but passes to the atmosphere.

3.1.20 Maximum Delivery Pressure

Highest gauge pressure that can be attained at the patient connection port when the apparatus is functioning normally.

3.1.21 Ventilatory Frequency

The number of ventilatory cycles per minute.

4 SYMBOLS

4.1 In addition to the symbols given in 3, the following symbols are used in this standard:

System dead space V_D , system
Oxygen concentration in bottle FO_2 , bottle

5 CONNECTORS

5.1 Patient Connection Port (see also Annex C)

The patient connection port of the resuscitator shall have 15 mm female and 22 mm male coaxial fittings.

5.2 Exhaust Port for Expired Air-Breathing Gases (see also Annex C)

If a tapered connector is provided at the exhaust port, it shall be a 30 mm male conical fittings or a 19 mm male conical fitting. The fitting shall incorporate a baulk, for example ridges in the internal lumen of the fitting.

NOTE — Such a baulk should not significantly increase the resistance to gas flow through the fitting.

5.3 Face Mask Fittings (see also Annex C)

Face masks shall have either a 22 mm female fittings or a 15 mm male fitting which will mate the corresponding fittings.

6 OPERATIONAL REQUIREMENTS

6.1 General

All performance requirements in this standard should be satisfied when the resuscitator is operated by one person, since frequently only one person is likely to be available to operate the resuscitator. This should be attainable when the resuscitator is used with either a face mask or an artificial airway device.

6.2 Dismantling and Reassembly (see also Annex C)

The manufacturer shall recommend a functional test of operation to be carried out after reassembly.

NOTE — A resuscitator intended to be dismantled by the user, for example for cleaning, etc, should be designed so as to minimize the risk of incorrect reassembly when all parts are mated.

6.3 Valve Function After Contamination with Vomitus (see also Annex C)

After the resuscitator has been tested in accordance with the test described in A-5.2 it shall meet all the requirements for the resuscitator being tested as laid down in 8.

NOTE — It is preferable that the valve housing be constructed so that operation of the mechanism may be observed by the operator. Observation of the functioning mechanism of the patient valve may assist the operator in detecting abnormal operation.

6.4 Mechanical Shock

6.4.1 Drop Test (see also Annex C)

If the resuscitator is intended to be operated outside of its carrying case, plastic bag, mounting bracket, etc, it shall meet all the requirements for the category of resuscitator being tested as laid down in 8, following the drop test described in A-5.3. If the resuscitator is intended for operation only inside its carrying case, it may be so tested, but the case shall be open and in its 'ready-for-use' condition.

6.5 Immersion in Water (see also Annex C)

After immersion in water by the method described in A-5.4, the resuscitator shall comply with all the requirements for the category of resuscitator being tested, laid down in 8, after 10 s of immersion in water.

7 PHYSICAL REQUIREMENTS

7.1 Size (see also Annex C)

A container, if provided, shall have a carrying handle or other device for lifting, and shall pass through a rectangular opening 300 mm × 400 mm in size.

7.2 Resuscitator Mass

The mass of the resuscitator container and contents (including any full gas cylinders) shall not exceed 14 kg.

8 PERFORMANCE

8.1 Supplementary Oxygen and Delivered Oxygen Concentration (For Gas-powered Resuscitators) (see Annex C)

When tested by the methods described in A-5.5, a gas-powered resuscitator shall deliver an oxygen concentration of at least 85 percent. If the resuscitator is capable of delivering other oxygen concentrations, the manufacturer shall state the conditions under which the various concentrations may be delivered.

8.2 Resistance to Breathing

See the requirement laid down by the manufacturer under 11.3.2(c).

8.3 Expiratory Resistance (see also Annex C)

When tested by the method described in A-5.6, the pressure generated at the patient connection port shall not exceed 0.5 kPa (= 5 cmH₂O) [see also 11.3.2(c)]

8.4 Inspiratory Resistance (see also Annex C)

When tested by the method described in A-5.7, the pressure at the patient connection port shall not exceed 0.5 kPa (5 cm H₂O) below atmospheric pressure [see also 11.3.2 (c)9].

8.5 Patient Valve Malfunction (see also Annex B)

When tested by the method described in A-5.8, the patient valve of the resuscitator shall not jam in the inspiratory position at an added input flow of up to 30 l/min when this flow is added in accordance with the manufacturer's recommendations.

8.6 Patient Valve Leakage — Forward Leakage (see also Annex C)

Where forward leakage is a design feature, it shall be so stated in the instruction manual.

8.7 Apparatus Dead Space (see also Annex C)

When tested by the test method described in A-5.9, the apparatus dead space shall not exceed 5 ml + 10 percent of the tidal volume specified for the resuscitator (see 8.8.1).

8.8 Ventilation Performance

8.8.1 Tidal Volume (see also Annex C)

The tidal volumes specified shall be delivered under the test conditions listed on Table 1 using the methods described in A-5.10, without the use of the override mechanism on any pressure-limiting system.

Table 1 Test Conditions
(Clause 8.8.1)

Designation	Compliance Classification ¹	Resistance Classification ¹	Inspiratory Expiratory Phase Time Ratio	Ventilatory Frequency	Minimum tidal Volume V _T , min ml
Adult	C 20	R 20	1 : 2	20	600

¹ See Annex B for a complete listing of compliance and resistance required for test.

8.9 Gas-powered Resuscitators

8.9.1 Pressure-limiting System (see Annex C)

A pressure-limiting system shall be incorporated in gas powered resuscitators which is supplied with gas at

the range of pressures specified in 10.6, the airway pressure shall not exceed 4.5 kPa (45 cm H₂O).

NOTE — A higher setting may be made available for certain patients, although the selection of such a setting requires experienced medical advice.

8.9.2 Manually-cycled, Gas-powered Resuscitators

Manually-cycled, gas-powered resuscitators shall meet the requirements laid down in 8.1.2, 8.8.1 and 8.9.1, when tested by the methods described in A-5.5, A-5.10 and A-5.11.

8.9.3 Automatic Pressure-cycled, Gas-powered Resuscitators

8.9.3.1 Manufacturer's warning (see also Annex C)

See 11.1.1.

8.9.3.2 Pressure-cycling system (see also Annex C)

Automatic pressure-cycled resuscitators shall have positive cycling pressures in the range of 2 to 3 kPa (20 to 30 cm H₂O) when tested by the method described in A-5.12.

NOTE — A negative-pressure phase may cause a decrease in arterial oxygen partial pressure (PO₂) or Functional Residual Capacity (FRC).

8.9.4 Automatic Time-cycled, Gas-powered Resuscitators

Automatic time-cycled, gas-powered resuscitators shall meet the requirements laid down in 8.1, 8.8.1 and 8.9.1, when tested by the methods described in A-5.5, A-5.10 and A-5.11.

8.9.5 Volume-cycled, Gas-powered Resuscitators

Volume-cycled, gas-powered resuscitators shall meet the requirements laid down in 8.1.2, 8.8.1 and 8.9.1, when tested by the methods described in A-5.5, A-5.10 and A-5.11.

8.10 Demand Valves

NOTE — These devices are subject to the requirements of this standard only when they are included as an integral part of a resuscitator.

8.10.1 Pressure for Initiation (see also Annex C)

When tested in accordance with the method described in A-5.17, the pressure drop needed to initiate gas flow shall be no more than a negative 0.2 kPa (2 cm H₂O).

8.10.2 Peak Inspiratory Flow (see also Annex C)

Demand flow shall terminate when airway pressure equals atmospheric pressure or at a pressure stated by the manufacturer, when tested by the methods described in A-5.15.

9 RESISTANCE TO ENVIRONMENT

9.1 Storage

The resuscitator and the resuscitator kit (if provided)

shall after storage at temperatures of -40°C and $+60^{\circ}\text{C}$ and at any relative humidity between 40 percent and 95 percent meet all the requirements for the category of resuscitator being tested as laid down in 8.

9.2 Operating Conditions (see also Annex C)

When tested by the methods described in A-5.16, the resuscitator shall meet all the requirements for the category of resuscitator being tested as laid down in 8, throughout the temperature range from -18 to $+50^{\circ}\text{C}$ and a humidity range from 40 to 95 percent relative humidity.

10 GAS SUPPLY

10.1 Gas Cylinders, Cylinder Valves and Yoke Connections

Gas cylinders, cylinder valves and yoke connections of the pin index type shall meet the requirements given in IS 3745 : 1978.

NOTE — Small cylinders with special fittings are frequently used in special situations.

10.2 Indication of Contents

Each gas supplied at cylinders pressure shall be monitored by a cylinder pressure gauge or contents indicator.

10.3 Captive Valve Key

A detachable, hand wheel, key or other device shall be made captive by means of a retaining chain or similar attachment capable of withstanding a static load of not less than 200 N (20 kg) without breaking.

10.4 Duration of Gas Supply (see also Annex C)

10.5 Connections for Compressed Gas (see also Annex C)

Gas connections between different gas services shall be non-interchangeable and shall not allow parts of the resuscitator to be incorrectly connected.

NOTE — If provided, a press-fit connection should give an easy and reliable connection with 6 mm internal diameter elastomeric tubing.

10.6 Supply Pressures (see also Annex C)

When supplied with gas at pressures between 270 and 550 kPa, the resuscitator shall meet all the requirements for the type of resuscitator being tested as laid down in 8. Testing shall be as described in A-5.

11 INFORMATION TO BE SUPPLIED BY MANUFACTURER

11.1 Marking

11.1.1 Manufacturer's Warning

For automatic pressure-cycled, gas-powered resuscitators, the manufacturer shall provide a warning on the resuscitator and the resuscitator case, and in

instructions for use that the unit is not designed to be used with closed-chest cardiac compression.

NOTE — Where possible, simple operating instructions should be provided on the resuscitator or the container.

11.1.2 Range of Supply Pressures

The range of supply pressures through which the resuscitator will operate shall be marked on the resuscitator.

11.1.3 Gas Source for Spontaneously Breathing Patient

The gas source supplying the spontaneously breathing patient, if it is other than the reservoir, shall be marked on the resuscitator.

11.2 Training

The instructions provided shall include a warning that the unit should only be used by persons who have received adequate training in resuscitation techniques.

11.3 Information to be Provided by the Manufacturer in Operating and Maintenance Instructions

11.3.1 General

The manufacturer shall provide a manual of operating and maintenance instructions. The size and shape of this (these) manual(s) shall be such that it (they) may be enclosed within or attached to the resuscitator container. Additional copies shall be available on request.

11.3.2 Contents

The manual shall be divided into sections to facilitate understanding of the instructions and shall include the following information:

- a) A warning that the resuscitator should be used only by persons who have received adequate training;
- b) Instructions on how to make the resuscitator operational in all intended modes of operation;
- c) A specification detailing the following information:
 - 1) Range of ventilatory frequency;
 - 2) Attainable delivery pressures;
 - 3) Operating environmental limits;
 - 4) Storage environmental limits;
 - 5) Delivered oxygen concentrations under various test conditions;
 - 6) Characteristics and/or dimensions of the gas inlet connection;
 - 7) Apparatus dead space (backward leakage and forward leakage, where appropriate);
 - 8) Expiratory resistance and inspiratory

resistance and any special fittings which impose such resistance;

- 9) The value of end-expiratory pressure generated by the resuscitation in normal use, if greater than 0.2 kPa (2 cm H₂O);
 - 10) Details of the pressure — limiting system and override mechanism operation, if any;
 - 11) External dimensions of the resuscitator and, if provided, the resuscitator case; and
 - 12) Mass of the resuscitator and, if provided, the resuscitator case.
- d) Instructions for dismantling and reassembly of components for cleaning and sterilization (if applicable). This shall include an illustration of the parts in their correct relationship. The manufacturer shall recommend a functional test of operation to be carried out after reassembly.
 - e) Recommendations for the preferred methods of cleaning and disinfection or sterilization of the resuscitator and its components;
 - f) A recommended functional test for operation to be carried out immediately prior to use;
 - g) A list of operator replaceable parts;
 - h) Recommendation for frequency of approved or factory service.

NOTE — If no service is required, this should also be stated in the manual.

- j) Resuscitator flow capabilities at 2kPa (20 cm H₂O) and at 4 kPa (40 cm H₂O) airway pressure;

- k) Recommendations for use in hazardous or explosive atmospheres, including a warning that if the resuscitator will entrain or permit the patient to inhale gas from the atmosphere, its use in containment is prevented — if applicable, the manufacturer shall describe how to prevent such entrainment or inhalation;
- m) Oxygen fire prevention — warnings shall be provided that in the presence of high oxygen concentrations there is danger from smoking or open flames and that oil should not be used with the resuscitator;
- n) Date of publication and/or revision of the manual;
- p) Duration of gas supply — the approximate duration of gas supply, expressed as time per litre cylinder volume when charged to the maximum nationally approved filling pressure and when the resuscitator is delivering a minute volume of 10 l/min (of the nearest setting to this):
 - at least 85 percent oxygen, and
 - the manufacturer selected value less than 85 percent oxygen, if the resuscitator is so capable.
- q) Range of supply pressures — the manufacturer shall state the range of supply pressures with which the resuscitator meets the applicable requirements laid down in 7 and shall describe any necessary adjustments for particular supply pressures.

ANNEX A

(Clauses 6.3, 6.4, 6.5, 8.1, 8.3, 8.4, 8.5, 8.7, 8.8.1, 8.9.2, 8.9.4, 8.9.5 and 8.10.2)

TEST METHODS

A-1 GENERAL TEST CONDITIONS

The ambient temperature for the duration of the tests shall be between 25 and 29 °C, except where otherwise stated. The relative humidity shall be within the range from 60 - 70 percent, except where otherwise stated.

A-2 APPARATUS

A-2.0 Typical test apparatus is shown in Fig. 1 to 5; alternative test apparatus of equivalent or greater accuracy may be used (see A-3).

A-2.1 Test Lung

(See Fig. 3 and 4 for example), with appropriate compliance and resistance characteristics (see Table 1).

A-2.2 Plug and Ring Gauges

15 mm, 22 mm and 32 mm sizes (see Fig. 1 for 32 mm gauge).

A-2.3 Resistors

If not provided with the test lung.

A-2.4 Pressure, Flow and Volume-Measuring and Recording Apparatus

Including a pneumotachograph.

A-2.5 Temperature – Measurement Apparatus

A-2.6 Deadspace – Measurement Apparatus

(See Fig. 2 for typical example).

A-2.7 Negative Pressure Generator

(See Fig. 5 for typical example).

A-2.8 Graduated Cylinder

Of at least 200 ml capacity.

A-2.9 Oxygen Analyser

A-2.10 Water Reservoir – 0.5 m deep.

A-2.11 Template – 300 mm × 400 mm.

A-2.12 Environmental Chamber

Capable of maintaining temperatures from – 40 to +60°C and relative humidity from 40 to 95 percent for periods of up to seven days.

A-2.13 Oxygen Supply

Capable of varying over the pressure range from

270 to 550 kPa and of producing a flow rate of at least 30 l/min.

A-2.14 Vacuum Source

Capable of producing flow rates from 5 to 50 l/min.

A-2.15 Gas Source

Capable of varying through the range of pressures from 270 to 550 kPa.

A-3 TEST APPARATUS TOLERANCES

A-3.1 Test apparatus shall have the following minimum tolerances:

- a) *Plug and Ring Gauges* – 15 mm, 22 mm sizes and 32 mm size (see Fig. 1).
- b) *Oxygen analyser* – ± 1 percent (v/v) of the concentration being measured with a response time of greater than 90 percent in 10 seconds.
- c) *Compliances* – ± 5 percent of required compliance value throughout a range of inspiratory phase times from 0.1 to 6.0 s (see Annex C).
- d) *Pressure, Flow and Volume* – ± 2.5 percent of the reading plus ± 2.5 percent of the full scale reading.
The reading accuracy of the associated recording device shall be maintained at a frequency of up to 10 Hz.
- e) *Resistances* – ± 20 percent for linear resistances and ± 10 percent for parabolic resistances within the designated flow range (see Annex B).
- f) *Temperature Measurement* – $\pm 0.5^\circ\text{C}$.

A-4 CONDITIONING AND REFERENCE CONDITIONS

A-4.1 Conditioning of the Resuscitator and Test Apparatus

Unless otherwise specified in particular tests, place the resuscitator and test apparatus in the test location and allow sufficient time for the resuscitator and apparatus to equilibrate with ambient conditions.

A-4.2 Reference Conditions

Correct all test readings to the reference conditions of NTPD (27 °C, 1 atm, 0 percent relative humidity).

A-5 TEST PROCEDURES

A-5.1 Dismantling and Reassembly

Verify by inspection of the resuscitator and accom-

panying documents that a functional test has been provided to test operation after reassembly.

A-5.2 Valve Function After Contamination with Vomitus

A-5.2.1 Test Material

A-5.2.1.1 Simulated vomitus

Prepared by mixing two parts of baby meal meat with vegetable meal and one part water.

A-5.2.2 Procedure

Pour 175 ml of simulated vomitus into the patient connection port and begin with 30 s, to operate the resuscitator for 30 cycles into the test lung (A-2.1) in order to disperse the vomitus. Clean the resuscitator of the mixture in accordance with the manufacturer's instructions for removal of vomitus. Ventilate the test lung (see Fig. 3 and 4 for typical illustrations of active and passive test lungs) at a frequency of 12 breaths/min for adult resuscitators and at a frequency of 30 breaths/min for infant resuscitators.

NOTE — Some of the test solutions may spill over when poured into the patient connection port.

A-5.3 Drop-Test

Drop the resuscitator from a height of at least 1 m on to a concrete floor in the worst case mode. For the purposes of this test, the resuscitator shall be a complete unit, including the face mask, valve, hose, regulator and cylinder, as appropriate. Perform the test with the cylinder empty.

A-5.4 Immersion in Water

Drop the resuscitator from a height of 1 m into the water reservoir (A-2.10). Take the resuscitator out after 10 s and shake out the water for not more than 30 s. Begin ventilating the test lung (A-2.1) immediately.

A-5.5 Delivered Oxygen Concentration for Gas-Powered Resuscitators

Connect the resuscitator to the test lung (A-2.1) set at C 20 and R 20 characteristics. Connect the oxygen analyser (A-2.9) at a site in the compliance chamber as far away as possible from the patient connection port. Ventilate the test lung at a frequency of 12 breaths/min and a tidal volume of 600 ml. Continue this procedure until a stable value for oxygen concentration is reached. Confirm that the resuscitator delivers an oxygen concentration of at least 85 percent (v/v). If the resuscitator is capable of delivering other oxygen concentrations, test the device at those settings recommended by the manufacturer and confirm that the oxygen concentration delivered to the test lung is within ± 10 percent of the set control value on the resuscitator.

This test shall be performed at the maximum and minimum flow settings recommended for the resuscitator.

A-5.6 Expiratory Resistance

Connect the patient connection port to the air/O₂ source and introduce air/O₂ flow rate of 50 l/min. Record the resistance generated at the patient connection port.

A-5.7 Inspiratory Resistance

Connect the patient connection port to a vacuum source producing an air/O₂ flow rate of 50 l/min. Record the inspiratory resistance generated at the patient connection port.

A-5.8 Patient Valve Malfunction

Connect the resuscitator to the test lung (A-2.1) set at C 20 and R 20 characteristics. Ventilate the test lung at a frequency of 12 breaths/min and a tidal volume of 600 ml. Using the oxygen supply (A-2.13), pass oxygen, as recommended by the manufacturer, at a flow rate of 30 l/min. Verify that the valve does not jam in the inspiratory position.

A-5.9 Apparatus Dead Space

A-5.9.1 Principle

Ventilation by the resuscitator of a 'bag-in-bottle' reservoir with 100 percent (v/v) oxygen as tracer gas. Calculate total dead space of the resuscitator from the volume of ventilation and the oxygen concentration of the inspired gas captured inside the bag.

A-5.9.2 Preparation of Apparatus Prior to Testing the Resuscitator

Set up the dead space measurement apparatus (A-2.6; see Fig. 2). Close the tap to the oxygen analyser (A-2.9). Open the ball valve. Connect the resuscitator and ventilate until the balloon fills the bottle completely and is pressed against the inner walls. Close the ball valve. Open the oxygen analyser tap. Open the flowmeter and fill the bottle with 100 percent (v/v) oxygen. Close the oxygen flowmeter when the pressure gauge reads approximately 1 kPa (10 cm H₂O). Connect the 22 mm/15 mm test connector to the 22 mm female socket and supply the appropriate flow of atmospheric air to the side nipple (see Table 2). Open the ball valve, whereby the expiratory flow path is flushed with 100 percent (v/v) oxygen. Ventilate the lung by covering and opening 10 mm diameter hole with a finger. Hold the tidal volume constant by means of the respirometer (V) and pressure gauge (P). The minimum number of ventilating cycles is given in Table 2. Close the ball valve and open the analyser tap. Adjust the 100 percent (v/v) oxygen flow to approximately 5 l/min. Record the reading for the oxygen concentration in the FO₂ bag of the oxygen analyser. Close off the oxygen flow when the pressure gauge reads 1 kPa (10 cm H₂O) again. This determination of internal dead space of the test apparatus shall be performed for every combination of test parameters used. The apparatus is now ready for testing the resuscitator.

Table 2 Test Parameters
(Clause A-5.9.2)

Tidal Volume V_T	Compliance C		Expiratory Resistance R _{exp}		Test Flow for Internal Dead Space	Test Cycles
	ml/kPa	(ml/cm H ₂ O)	kPa/(l.s)	[cm H ₂ O/(l.s)]		
ml					l/min	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
600	200	(20)	0.5	[5]	30	> 15
100	100	(10)	2	[20]	5	> 50

A-5.9.3 Procedure

Test the resuscitator using the same procedure as described for the test connector (see A-5.9.2).

A-5.9.4 Expression of Results

Calculate the system dead space, that is, with test connection using the following equation:

$$V_{D, \text{system}} = \frac{FO_2 \text{ bag (test connection)} - 21}{79} \times V_T$$

NOTE – The apparatus should be so designed that $V_{D, \text{system}}$ is 20 ml. The oxygen analyser should be calibrated to read 21 percent with atmospheric air and be accurate within ± 1 percent (v/v) oxygen up to 30 percent (v/v) oxygen.

Calculate the apparatus dead space of the resuscitator being tested using the following equation:

Apparatus dead space,

$$V_{D, \text{app}} = \frac{FO_2 \text{ bag} - 21}{79} \times V_T - V_{D, \text{system}}$$

A-5.10 Tidal Volumes

Connect the resuscitator to the appropriate test lung (A-2.1; see Fig. 3 and 4) having the characteristics stated in Table 1. Measure the volume by recording the flow resulting from compression of the compressible unit by means of a pneumotachograph (A-2.4) connected between the simulated resistance and compliance of the standard lung and integrating the recorded flow (other equivalent method may be used). Use only one hand to compress the compressible unit. Perform these tests without the use of an over ride mechanism if one is provided.

A-5.11 Pressure-limiting System (Gas-Powered Resuscitators)

For resuscitators for use with adults and equipped with pressure-limiting systems, occlude the adult connection port and pass air at a flow rate of 60 l/min or at the maximum flow rate which the resuscitator is capable of, whichever is greater.

A-5.12 Pressure-cycling System (Automatic, Pressure-cycled, Gas-Powered Resuscitators)

Connect the resuscitator to the appropriate test lung (A-2.1; see Fig. 3 and 4) having the stated characteristics in Table 1. Activate the resuscitator and record the

pressure at which the device cycles from inspirator to expiration.

A-5.13 Pressure for Initiation (Demand Valves)

Connect the patient port of the resuscitator to the negative pressure generator (A-2.7; see Fig. 5). Measure the pressure between the demand valve and the negative pressure generator. Record the point at which flow from the demand valve begins.

A-5.14 Peak Inspiratory Flow

Connect the demand valve to be tested as shown in Fig. 5 and carry out the test procedure described in A-5.14.1 to A-5.14.3.

A-5.14.1 Flow Threshold

Set the negative pressure, P_{neg} , by adjusting the regulator which controls the negative input pressure, P_{neg} until the output flow, $q_{v,o}$, is between 0 and 10 l/min. The reading on the negative pressure gauge (P) should be between -0.2 and 0 kPa (2.0 and 0 cm H₂O).

A-5.14.2 Peak Flow

Set the negative pressure, P_{neg} , by adjusting the regulator which controls the negative input pressure, P_{neg} until the output flow, $q_{v,o}$, is 100 l/min. The reading on the negative pressure gauge (P) should be between -0.5 and 0 kPa (-5.0 and 0 cm H₂O).

A-5.14.3 Flow Termination

Set the negative pressure, P_{neg} , by adjusting the regulator which controls negative input pressure P_{neg} until the output flow $q_{v,o}$ is between 0 and 0.5 l/min. Read and record the reading on the negative pressure gauge (P).

A-5.15 Termination Pressure

Using the method described in A-5.13, determine the airway pressure at which the demand flow ceases and record that pressure.

A-5.16 Operating Condition

A-5.16.1 General

Following completion of each phase of this test, the resuscitator shall be operated under the conditions described in the general requirements and also under

the specific conditions for the category of resuscitator being tested, that is gas-powered volume cycled, hand-powered, etc, laid-down in 9.2.

A-5.16.2 Procedure

A-5.16.2.1 Prepare the test resuscitator in accordance with the general requirements. Place the resuscitator system in the environmental chamber (A-2.12) set at 50 °C and at least 95 percent relative humidity. Maintain these conditions for no fewer than seven days. At the end of this period, operate and test the resuscitator. Once testing has been completed, return the resuscitator, within 5 min, to ambient conditions of 18 to 22 °C and 40 to 70 percent relative humidity for a period of no fewer than seven days. At the end of this period, operate and test the resuscitator.

A-5.16.2.2 Place the resuscitator system in the environmental chamber set at - 40 °C for a period of at least 4 h or until the test item stabilizes. At the end of this period, return the resuscitator, within 5 min, to an ambient temperature between 18 and 22 °C. Allow the resuscitator to stabilize for at least 4 h. At the end of this period, operate and test the resuscitator.

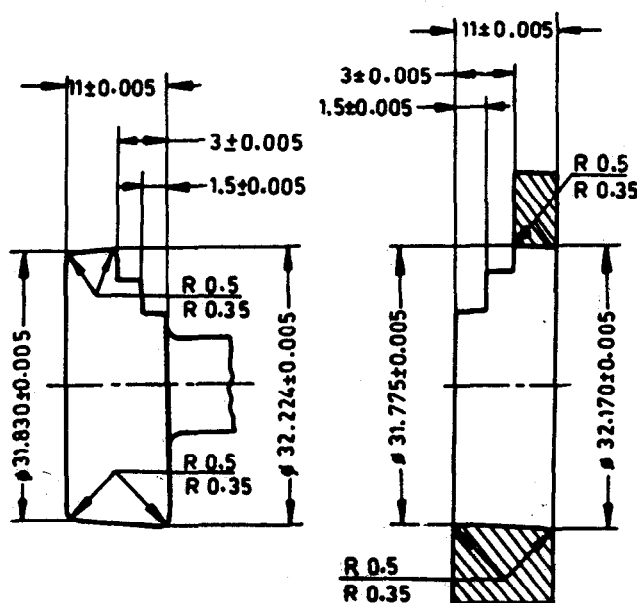
A-5.16.2.3 Place the resuscitator system in the environmental chamber at +60 °C and at 40 to 70 percent relative humidity for a period of not less than 4 h. At the end of this period, return the resuscitator, within 5 min, to ambient conditions of 18 to 22 °C and 40 to 70 percent relative humidity. Allow the resuscitator to stabilize for 4 h. At the end of this period, operate and test the resuscitator.

A-5.16.2.4 Place the resuscitator system in the environmental chamber set at - 18 °C for 4 h. At the end of this period, operate and test the resuscitator. Once testing has been completed, return the resuscitator to ambient conditions of 18 to 22 °C. Within 5 min, operate and test the resuscitator.

NOTE — In each of the operational tests prescribed, the resuscitator should be operated continuously for a period of at least 10 min.

A-5.17 Supply Pressures

Connect the resuscitator to the gas source (A-2.15) and test its performance at source pressures of 270 kPa and 550 kPa using the test methods described for the general requirements and any specific requirements for the type of resuscitator being tested as laid down in 8.10.1.



NOTES

- 1 Basic taper is 1 : 28 on diameter.
- 2 Engagement is 9.5 NOM.

All dimensions in millimetres.

FIG. 1 PLUG GAUGES

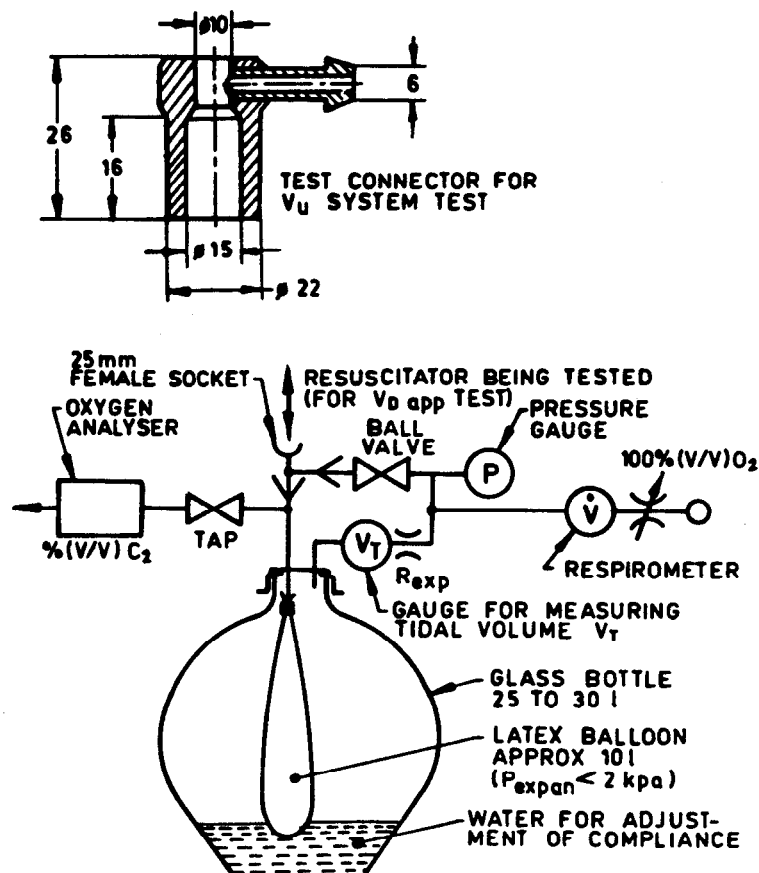


FIG. 2 TEST SET-UP FOR MEASURING TOTAL APPARATUS DEAD SPACE

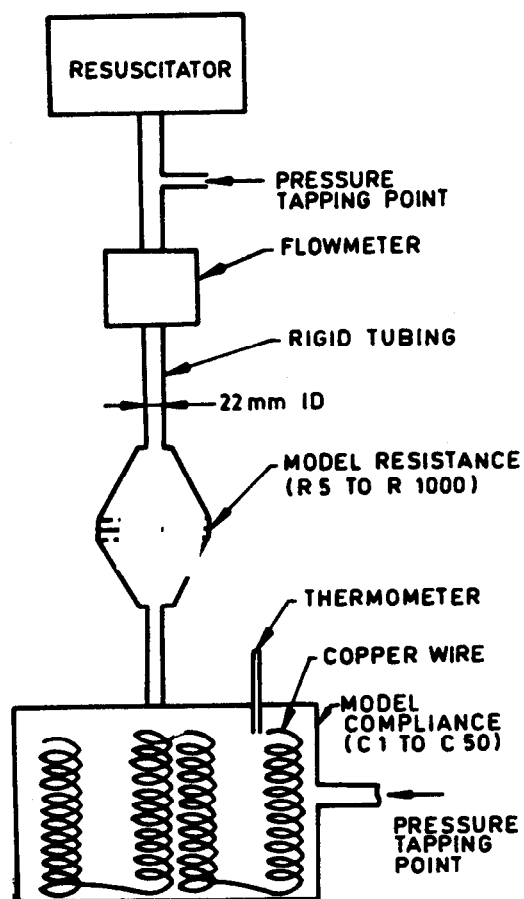


FIG. 3 REPRESENTATIVE PASSIVE TEST LUNG SYSTEM

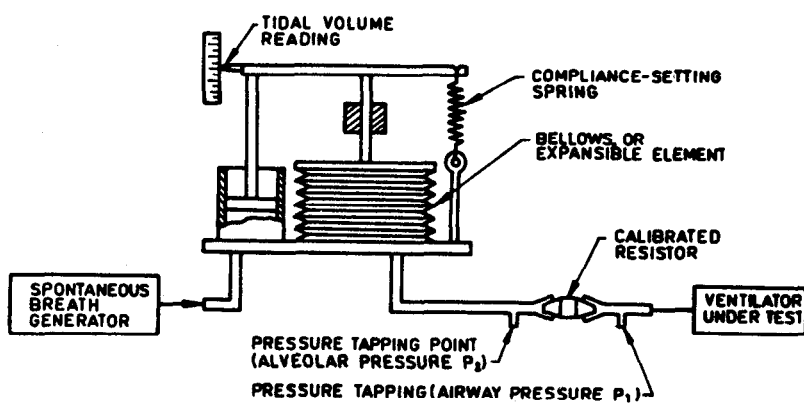


FIG. 4 REPRESENTATIVE ACTIVE TEST LUNG SYSTEM

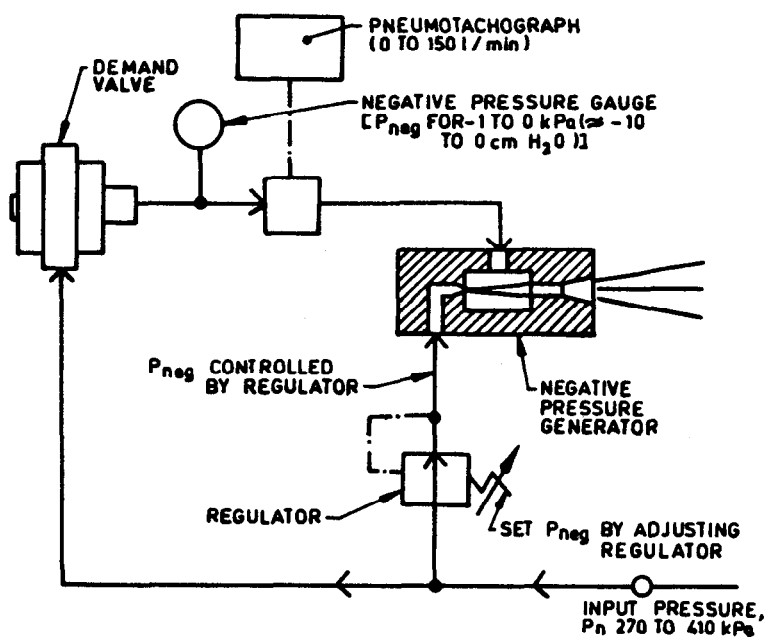


FIG. 5 TEST SET-UP FOR TESTING DEMAND VALVES (THRESHOLD AND PEAK FLOWS)

ANNEX B
(Clauses 8.5 and A-3.1)

COMPLIANCES AND RESISTANCES REQUIRED TO SET UP TEST LUNG

Table 3 Required Compliances

Classification ¹⁾	Compliance	
	C	
	ml/kPa	(ml/cmH ₂ O)
C 50	500	(50)
C 20	200	(20)
C 10	100	(10)

¹⁾ The classification was originally based on conventional centimetres of water.

Table 4 Required Resistances

Classi- fication ¹	Resistance				Range of Air Flow ³⁾ (for linear or parabolic resistances)
	Linear		Parabolic ²⁾		
	R		R _p		
	kPa/ (l.s)	(cmH ₂ O/ (l.s)	kPa/(l.s) (l.s)	(cmH ₂ O/ (l.s)	
				1/s	
R 5	0.5	(5)	0.77	(7.7)	0 to 2.0
R 20	2	(20)	0.56	(5.6)	0.5 to 1.0
R 50	5	(50)	0.39	(3.9)	0.25 to 0.5
R 400	40	(400)	0.14	(1.4)	0.05 to 0.07

¹⁾ The classification was originally based on conventional centimetres of water.

²⁾ The values for parabolic resistance refer to the nominal inside diameter of tin plate, sharp-cornered orifices needed to achieve these resistance values. Other geometric shapes may be used, for example, thicker orifices with rounded corners but nominal diameters would be different.

³⁾ The tolerances for the flow range values are +20 percent for linear resistances and +10 percent for parabolic resistances.

ANNEX C

(Clauses 5.1, 5.2, 5.3, 6.2, 6.3, 6.4, 1, 6.5, 7.1, 8.1, 8.3, 8.4, 8.6, 8.7, 8.9.1,
8.10.2, 10.4, 10.5 and 10.6)

RATIONALE STATEMENT

C-1 PATIENT CONNECTOR

C-1.1 The patient connector dimensions permit connection with standard 15 mm tracheal tube connectors and face mask fittings having a 22 mm female socket or 15 mm male fittings.

C-1.2 Exhaust Port for Expired Air/Breathing Gases

The exhaust connection described is that used for connection to the transfer tubes of anaesthetic gas scavenging systems. It is essential that breathing system conical fittings are not compatible with this port. It is also important that the exhaust port be designed

such that it cannot be confused with the inspiratory port during use of the resuscitator.

C-1.3 Face Mask Fittings

It is important that resuscitator face masks should be generally interchangeable.

C-2 DISMANTLING AND REASSEMBLY

Wrongly assembling a resuscitator so that it causes incorrect operation or complete malfunction which may result in inadequate ventilation of the patient.

C-2.1 Valve Function after Contamination with Vomitus

It is important that vomit can be quickly and effectively cleared from a resuscitator so that resuscitation can be continued with a minimum of interruption.

C-2.2 Drop Test

It is important that resuscitators can withstand severe shock caused by falls from ambulances, hospital beds, etc.

C-2.3 Immersion in Water

Resuscitators are often used in areas where the device may be inadvertently dropped into water during the resuscitation. If the unit is recovered quickly from the water, it should still function.

C-3 SIZE

C-3.1 Resuscitators may be required where access to patients is difficult, such as in crawl spaces and through manholes.

C-4 OPERATOR-POWERED RESUSCITATORS

C-4.1 Although 40 percent (v/v) oxygen concentration is adequate under some circumstances, 85 percent (v/v) or higher oxygen concentrations are preferable for the treatment of severely hypoxemic patients during resuscitation. This concentration should be achievable at supplementary oxygen flows of 15 l/min or less because to specify greater than 15 l/min would exceed the normal calibration to standard, clinically used flowmeters for adult use and could potentially lead to inaccurate control of oxygen flows and jamming of the patient valve in the inspiratory position.

C-4.2 Gas-Powered Resuscitators

High oxygen concentrations are important in resuscitating patients who are extremely hypoxemic. Lower percentages of oxygen will lengthen the duration of oxygen supply. The performance of air-entrainment, "mixing" devices is influenced by the flow settings of the resuscitator and the compliance and resistance of the patient.

C-4.3 Expiratory Resistance

To facilitate exhalation, expiratory resistance should be minimized unless there are special clinical indications to impose such resistance.

C-4.4 Inspiratory Resistance

The design of a resuscitator should be such that it is possible for the patient to breath spontaneously without excessive sub-atmospheric pressure when the resuscitator is applied to the patient's airway but is not activated by the operator.

C-4.5 Patient Valve Malfunction

Valve malfunction or jamming in the inspiratory position at high supplementary oxygen flow may lead to failure of the resuscitator and transmission of excessive

pressures to the patient. Resuscitators are commonly used at oxygen input flows of 15 l/min, but flowmeter valves are often capable of permitting flows of over 30 l/min. It is essential to follow the manufacturer's instructions and to use only attachments recommended for use with the resuscitator.

C-4.6 Patient Valve Leakage – Forward Leakage

If forward leakage is a design feature of a resuscitator, it should be disclosed so that the user does not confuse this leakage with a malfunction.

C-4.7 Apparatus Dead Space

It is essential to minimize apparatus dead space in order to limit rebreathing of expired gases.

C-4.8 Tidal Volume

For adult ventilation a typical tidal volume is approximately 600 ml. The compliances and resistances listed in Table 1 are representative of the possible compliances and resistances found in adults needing resuscitation. The ventilatory frequency is a typical value used in adult resuscitation.

C-4.8.1 Pressure Limitation (Operator-Powered Resuscitators)

Experience with infant resuscitation suggests that a maximum inspiratory pressure of 4.5 kPa (45 cm H₂O) will not produce lung damage and will permit adequate tidal volumes in most patients weighing under 10 kg. Pressure-limiting systems are not mandatory on operator-powered resuscitators designated for use with patients weighing over 10 kg. However, it is essential that resuscitators with such systems satisfy the tidal volume requirements laid down in this standard (see Table 1) without the use of any override mechanism. When airway pressure is limited to below 6 kPa (60 cm H₂O), it was felt that an override mechanism is essential in order to ventilate those patients with low lung compliance and/or high airways resistance.

C-4.8.2 Pressure-Limiting System

It is essential that maximum delivery pressure is limited on all gas powered resuscitators. Airway pressure at 4.5 kPa (45 cm H₂O) was considered adequate for ventilation of the lungs, but unlikely to produce barotrauma. The selection of higher settings for difficult clinical problems necessitates risk of barotrauma.

C-4.8.2.1 Manufacturer's warning

These resuscitators are unacceptable for use during closed cardiopulmonary resuscitation because the increased intrathoracic pressure caused during chest compression causes the resuscitator to cycle from the inspiratory mode to the expiratory mode prior to adequate ventilation of the lungs.

C-4.8.2.2 Pressure-cycling system

It is required that pressure cycled resuscitators meet the performance requirements of this International

Standard, but they are of limited use on patients with poor lung compliance and/or high airways resistance because the cycling pressure is achieved without adequate ventilation. A 'negative' pressure phase should not be used as it is associated with a fall in functional residual capacity (FRC) and arterial oxygen partial pressure (p₂).

C-4.9 Pressure for Initiation

It is important that the patient should not have to generate large amounts of negative pressure to initiate gas flow from the demand valve in order to minimize respiratory work. A negative pressure of - 0.2 kPa (2 cm H₂O) is physiologically acceptable.

C-4.10 Peak Inspiratory Flow

Peak flows as outlined in this cause are necessary in order to satisfy the inspiratory needs of the typical patient; large amounts of negative pressure should not be required to generate these flows as it would cause fatigue in a spontaneously breathing patient.

C-4.11 Termination Pressure

Positive pressure indicates that adequate tidal volume has been delivered. When the pressure becomes slightly positive it indicates that the patient should be allowed to exhale and hence flow should stop.

C-4.12 Operating Conditions

Resuscitators can be expected to be exposed to the temperature extremes outlined in 9.2 since such temperatures frequently occur throughout the world in environments where resuscitators are used.

C-4.13 Duration of Gas Supply

Small, easily portable cylinders are commonly used with resuscitators. It is important that the operator have some idea of the duration of this size of oxygen supply under simulated conditions of use. In case of mines the duration shall not be less than 40 minutes.

C-4.14 Connections for Compressed Gas

The fresh gas nipple are intended to minimize disconnections. It is essential to be able to easily connect resuscitator oxygen tubing, for example while the resuscitator is in use.

C-4.15 Supply Pressure

The range of supply pressures reflect the variety of pressures used internationally and the tolerances of pressure-regulating systems.

ANNEX D (Foreword)

MATERIALS

D-1 CLEANING AND DISINFECTION OR STERILIZATION

D-1.1 Components which are subject to contamination should withstand the methods of cleaning and disinfection or sterilization recommended by the manufacturer or be labelled 'for single use only' (disposable).

D-2 OXYGEN COMPATIBILITY

D-2.1 All resuscitator components should be compatible with and resistant to ignition with oxygen concentrations and pressures to which the component is exposed.

D-3 RESISTANCE TO CORROSION AND DETERIORATION

D-3.1 Resuscitator performance should not be degraded because of corrosion during a period of 12 months after being stored in accordance with the manufacturer's instructions.

D-4 PATIENT VALVE HOUSING

D-4.1 The valve housing should be constructed of materials such that the functioning mechanism is readily visible to the operator.

D-5 RATIONALE

D-5.1 Cleaning and Disinfection or Sterilization

Resuscitators are likely to become contaminated by bacteria and foreign matter during use. It is therefore essential that manufacturer's recommended suitable methods of cleaning and disinfection or sterilization for many applications, cleaning and disinfection alone is adequate. However, in certain situations, the user may require resuscitators which can withstand steam or ethylene oxide gas sterilization of the contaminated components. The user should appreciate that some methods of disinfection and sterilization may shorten the usable life of the resuscitator.

D-5.2 Oxygen Compatibility

Selection of materials for use in high oxygen concentrations, especially at elevated supply pressures, involves consideration of both compatibility and ease of ignition. Materials that burn in air will burn violently in high concentrations of oxygen at atmospheric pressure and may explode at higher pressures. Many materials, including metals, will not burn in air but may do so in pure oxygen, particularly under pressure. Materials may be ignited by the friction of a valve seat or stem packing or by the adiabatic compression produced when oxygen at high pressure is

suddenly introduced into a system at low pressure. Therefore, easily ignitable materials, such as some rubber and plastics, should be avoided in valves and fittings, especially in high-pressure oxygen systems, unless tested or experience-rated for such service. These conditions and requirements also apply to the use of nitrous oxide.

D-5.3 Resistance to Corrosion and Deterioration

Since resuscitators are often stored and used in the proximity of sea water, it is important that resuscitators are capable of meeting the performance requirements of this standard after being used and stored in such an environment.

ANNEX E

(Foreword)

FACE MASKS

A face mask provided with or recommended for use with a resuscitator should comprise a body and a face seal, and a port to receive the patient connector of the resuscitator. The face seal should be capable of provided a fit which minimizes leaks at the operating

pressures and temperatures specified in this standard. The body of the mask should be transparent to allow the operator to observe the patient's nose and mouth for breath condensation as evidence of breathing and also for the possible appearance of vomitus.

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